

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 45D2087705	(X3) Date Survey Completed 08/30/2023
Name of Provider or Supplier Alamo Heights Complete Care	Street Address, City, State 6496 N New Braunfels Ave, San Antonio, TX	
For information on the provider's plan to correct this deficiency, please contact the provider or the state survey agency.		

(X4) ID Prefix Tag	Summary Statement of Deficiencies
D0000	A recertification survey was performed on August 30, 2023. The laboratory was found to be in compliance with the CLIA regulations found at 42 CFR, with standard level deficiencies cited.
D5209	<p>PERSONNEL COMPETENCY ASSESSMENT POLICIES CFR(s): 493.1235</p> <p>As specified in the personnel requirements in subpart M, the laboratory must establish and follow written policies and procedures to assess employee and, if applicable, consultant competency.</p> <p>This STANDARD is not met as evidenced by: Based on a review of the submitted CMS form 209, laboratory policy, and confirmed in staff interview, the laboratory failed establish and follow a policy for assessing the competency for 1 of 1 Technical Consultants. Findings included: 1. A review of the submitted CMS form 209 listed one Technical Consultant. 2. A request was made for a policy for assessing the competency of Technical Consultants. No policy was provided. 3. During an interview on 08/30/2023 at 1030 hours in the breakroom, after review of the above records, the Technical Consultant confirmed the findings.</p>
D5545	<p>HEMATOLOGY CFR(s): 493.1269(b)(d)</p> <p>(b) For all nonmanual coagulation test systems, the laboratory must include two levels of control material each 8 hours of operation and each time a reagent is changed. (d) The laboratory must document all control procedures performed, as specified in this section.</p> <p>This STANDARD is not met as evidenced by:</p>

Based on direct observation, a review of Triage patient records, review of Triage quality control records, and confirmed in staff interview, the laboratory failed to perform 2 levels of D-dimer controls within 8 hours prior to performing patient testing for 4 of 72 patients. Findings included: 1. During a tour of the laboratory on 08/30/2023 at 0845 hours, 1 Triage (serial number 74881) was observed. 2. A review of patient and quality control records for the D-dimer testing performed on the Triage instrument (June 01, 2023 through July 31, 2023) revealed the following: Patient ID 7202315 Patient test date and time: 07/20/2023 at 1755 hours Last completed quality control: 07/20/2023 at 0950 hours Total elapsed time: 8 hours and 5 minutes Patient ID 6252307 Patient test date and time: 06/25/2023 at 1358 hours Low level quality control completed: 06/25/2023 at 1324 hours Only 1 level of quality control was completed before performing patient testing. Patient ID 6222301 Patient test date and time: 06/22/2023 at 0217 hours Last completed quality control: 06/21/2023 at 1001 hours Total elapsed time: 15 hours and 26 minutes Patient ID 6172306 Patient test date and time: 06/17/2023 at 1120 hours Last completed quality control: 06/17/2023 at 0318 hours Total elapsed time: 8 hours and 2 minutes The laboratory failed to perform 2 levels of D-dimer quality control within 8 hours prior to performing patient testing. 3. During an interview on 08/30/2023 at 1145 hours in the breakroom, after review of the above records, Technical Consultant #1 confirmed the findings.

D6055

TECHNICAL CONSULTANT RESPONSIBILITIES
CFR(s): 493.1413(b)(9)

The technical consultant is responsible for evaluating and documenting the performance of individuals responsible for moderate complexity testing whenever test methodology or instrumentation changes. The individual's performance must be reevaluated to include the use of the new test methodology or instrumentation prior to reporting patient test results.

This STANDARD is not met as evidenced by:
Based on a review of laboratory records, personnel records, and confirmed in staff interview, the Technical Consultant failed to evaluate employee competency prior to performing patient testing for 11 of 14 Testing Personnel (TP). Findings included: 1. A review of laboratory records revealed the laboratory changed to a Sysmex XP-300 (serial number C4550) for hematology testing in February 2022. 2. A review of personnel records (TP#1 - TP#14, as listed on the submitted CMS form 209) revealed the following training and competency records for the Sysmex XP-300: TP#1 Initial training on the Sysmex XP-300 completed 02/25/2022 Initial Sysmex XP-300 competency assessment completed 07/26/2022 TP#2 Initial training on the Sysmex XP-300 completed 02/25/2022 Initial Sysmex XP-300 competency assessment completed 09/30/2022 TP#3 Initial training on the Sysmex XP-300 completed 02/25/2022 Initial Sysmex XP-300 competency assessment completed 10/08/2022 TP#5 Initial training on the Sysmex XP-300 completed 02/25/2022 Initial Sysmex XP-300 competency assessment completed 12/17/2022 TP#6 Initial training on the Sysmex XP-300 completed 02/25/2022 Initial Sysmex XP-300 competency assessment completed 10/18/2022 TP#7 Initial training on the Sysmex XP-300 completed 02/25/2022 Initial Sysmex XP-300 competency assessment completed 09/28/2022 TP#9 Initial training on the Sysmex XP-300 completed 07/01/2022 Initial Sysmex XP-300 competency assessment completed 08/02/2022 TP#10 Initial training on the Sysmex XP-300 completed 02/25/2022 Initial Sysmex XP-300 competency assessment completed 09/15/2022 TP#12 Initial training on the Sysmex XP-300 completed 02/25/2022 Initial Sysmex XP-300 competency assessment completed 05/26/2022 TP#13

Initial training on the Sysmex XP-300 completed 02/25/2022 Initial Sysmex XP-300 competency assessment completed 07/30/2022 TP#14 Initial training on the Sysmex XP-300 completed 02/25/2022 Initial Sysmex XP-300 competency assessment completed 03/16/2022 The Technical Consultant failed to assess testing personnel competency prior to performing patient testing after a change in hematology instrumentation. 3. In an interview at 1000 hours in the breakroom, after review of the above records, Technical Consultant #1 (as listed on CMS form 209) confirmed the findings. Word Key: CMS = Centers for Medicare and Medicaid Services